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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,657	03/16/2004	Kazutami Sakamoto	250521US0CONT	1130
22850	7590	12/28/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			WILLIAMS, LEONARD M	
			ART UNIT	PAPER NUMBER
			1617	
DATE MAILED: 12/28/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

10/800,657

Applicant(s)

SAKAMOTO ET AL.

Examiner

Leonard M Williams

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

The examiner notes that this is a continuation of application 10/055,951 filed on 01/28/2002 now abandoned.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Baldacci (U.S. Patent No. 4581371).

The examiner respectfully points out that the term “promoter” used by the applicant in claims 1-2 and 5-6 is being read as a compound and/or composition for purposes of evaluating the merits of said claims.

It is respectfully pointed out that the recitation “for the production of nitric oxide in a living body” and “for the production of nitric oxide synthase in a living body” has not been given patentable weight because these recitations occur in the preamble.

A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the

process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Baldacci, in col. 1 lines 15-35 and claim 1, teach an immunomodulating composition comprising L-arginine, L-lysine, and their salts with L-2-pyrrolidone-5-carboxylic acid anticipating the "...promoter..., comprising, as an active ingredient, at least one selected from the group consisting of pyrrolidonecarboxylic acid, a pyrrolidonecarboxylic acid salt, and a pyrrolidonecarboxylic acid derivative" of claims 1 and 5, and the "...promoter...which further comprises arginine as another active ingredient..." of claims 2 and 6.

Baldacci, in col. 2 line 55 to col. 3 line 10, teach a pharmaceutical composition containing L-2-pyrrolidone-5-carboxylate of L-arginine, L-2-pyrrolidone-5-carboxylate of L-lysine, potassium iodide, sodium benzoate, fructose, ascorbic acid, sodium metabisulfite, lemon flavor, and deionized water anticipating the "...cosmetic or pharmaceutical composition...comprising...at least one selected from the group consisting of pyrrolidonecarboxylic acid, a pyrrolidonecarboxylic acid salt, and a pyrrolidonecarboxylic acid derivative" of claims 3 and 7, and the "...cosmetic or pharmaceutical composition...which further comprises arginine as another active ingredient..." of claims 4 and 8.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Noel (U.S. Patent No. 5141964).

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Noel, in example 3, teaches a cosmetic composition comprising chitosan, gluconic acid, pyrrolidonecarboxylic acid, glucosamine HCl, arginine, and absorbed water anticipating the "...promoter..., comprising, as an active ingredient, at least one selected from the group consisting of pyrrolidonecarboxylic acid, a pyrrolidonecarboxylic acid salt, and a pyrrolidonecarboxylic acid derivative" of claims 1 and 5, the "...promoter...which further comprises arginine as another active ingredient..." of claims 2 and 6, the "...cosmetic or pharmaceutical composition...comprising...at least one selected from the group consisting of pyrrolidonecarboxylic acid, a pyrrolidonecarboxylic acid salt, and a pyrrolidonecarboxylic acid derivative" of claims 3 and 7, and the "...cosmetic or pharmaceutical composition...which further comprises arginine as another active ingredient..." of claims 4 and 8.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG
PRIMARY EXAMINER

LMW